

# OLYMPIC

5900 First Ave. So. • Seattle, WA 98108 • USA



# MEDICAL

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December 10, 1999

## PRIORITY MAIL

Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources & Management Services  
Food & Drug Administration  
5603 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

Docket Number 99N-4491

Dear Sir or Madame:

The following comments are in reference to docket number 99N-4491, FDA's Proposed Strategy on Reuse of Single-Use Devices (SUDs).

Olympic Medical Corp. is a manufacturer of machinery used to reprocess (wash and high-level disinfect), respiratory therapy and anesthesia breathing circuits and related components, e.g., rubber, plastic and silicone tubes, face masks, breathing bags, humidifiers, nebulizers, resuscitation bags, etc.

When Olympic Medical introduced the first washer/pasteurizer in 1976, most of the above-mentioned equipment used in U.S. hospitals were, almost universally, reusable. Beginning in the early 1980s, and fueled by the early, uninformed days of the AIDS epidemic, most U.S. hospitals began a slow steady shift to disposables.

Today, at great expense to the consumer and environment, this equipment is now disposable in about 95 per cent of all U.S. hospitals. Some of these hospitals, however, continue to use our machinery to reprocess the disposable versions of this equipment. They know from experience that most of these disposable items will easily withstand the disinfection process provided by our machines. And, they realize that even if they can reprocess an item only once, they have cut their budget for that item by 50 percent. Furthermore, reusable versions of the equipment they require may no longer be available.

North of the border in Canada, this practice has become almost universal when it comes to respiratory therapy and anesthesia equipment. Virtually every large hospital in Canada uses our machinery to safely reprocess a mixture of reusable and disposable equipment. In fact, many of these hospitals have told me they will not even consider implementing a new item, disposable or reusable, unless they first test it for durability through our machines. This practice is not only

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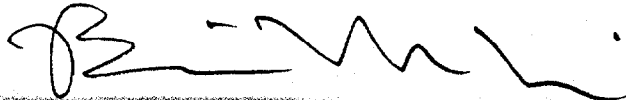
environmentally responsible, but saves the taxpayer millions of dollars every year without jeopardizing patient safety. In fact, most Canadian hospitals have committees dedicated to evaluating the safety and cost effectiveness of reprocessing individual disposable items.

We are very pleased to see the FDA address this issue head-on, in particular its plan to explore developing a "device categorizing system based on the level of risk presented by reprocessing and reusing SUDs." Currently, the items addressed in this letter are classified as Class I Exempt and, in our opinion, represent a "low-risk" with regard to reprocessing.

Another commonly reprocessed SUD not mentioned on your list of "Frequently Reprocessed SUDs" is the compressible limb sleeve. This is currently a Class II item that has proved to be very safely and cost effectively reprocessed through our machines, as well as other well established reprocessing methods. Once again, it is our opinion that this SUD represents a low risk with regard to reprocessing.

Please contact me on 1-800-426-0353 Ext. 5159, or [bmcnair@olymed.com](mailto:bmcnair@olymed.com), if I can be of additional assistance on this issue.

Sincerely,

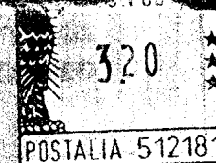
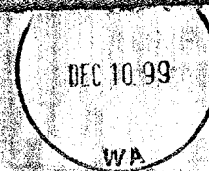


Brian McNair  
National Sales Manager

BM/eh

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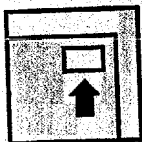
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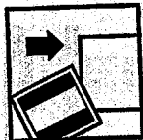
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